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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,516      | 11/21/2003  | Yiwen Tang           | 50623.304           | 3018             |

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7590 07/02/2009

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| EXAMINER |
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ROGERS, JAMES WILLIAM

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| ART UNIT | PAPER NUMBER |
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1618

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07/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/719,516 | <b>Applicant(s)</b><br>TANG ET AL. |  |
|                              | <b>Examiner</b><br>JAMES W. ROGERS   | <b>Art Unit</b><br>1618            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-8,11-18,20,21,23-25 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-8,11-18,20,21,23-25 and 28-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/08/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,6-8,11,15,17-18,20-21,23-25,28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 01/21229 A1), for the reasons set forth in the office action mailed 04/18/2008.

Claims 1-3,6-8,11-18,20,23-25,28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (EP 0 970,711 A2), for the reasons set forth in the office action mailed 04/18/2008.

Claims 1-3,6-8,11,15,17-18,20,23-25,28,32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by DeSimone et al. (US 2004/0181271 A1), for the reasons set forth in the office action mailed 04/18/2008.

Regarding the new limitations within claims 33-34, DeSimone specifically teaches the use of poly(L-lactide). See [0035] and claims 38-39,73 and 74.

Claims 1-3,6-8,11,15,17-18,20,23-25,28,32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 2001/0014717 A1, '717 from hereon), for the reasons set forth in the office action mailed 04/18/2008.

Regarding the new limitations within claims 33-34, Hossainy specifically teaches the use of poly(L-lactide). See [0041], [0051].

Applicant's arguments filed 06/08/2009 have been fully considered but they are not persuasive.

Applicants assert that Lee, DiSimone, Hossainy and, '717 cannot anticipate their claims because none of the references recite every feature of their claimed invention. Applicants assert that none of the references describe the polymers as having the same Tg or degree of crystallization presently claimed for the first polymer and polymeric additive. In order to bolster their argument applicants submitted two references which they purport support their argument that the degree of crystallinity can be different for a

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particular polymer and depends upon the conditions under which the polymer was made.

The relevance of these assertions is unclear. As detailed in previous office actions it is the position of the examiner that since the polymers taught in the references above are the same as applicants claimed polymers (PCL, PLA and PGA) they will inherently have the same properties including  $T_g$  and degree of crystallization. Applicants have not set forth in their claims or within the specification how their polymers would have a different degree of crystallization and  $T_g$  than those same polymers known in the art or that are commercially available. The references presented by applicants do indeed show that polymers with different molecular weights (size) and particle sizes do exhibit different degrees of crystallization, however applicants have not recited within their claims any physical feature of the polymers (MW or particle size) that would exclude the polymers within the references above. The examiner can only search for what is claimed, since the polymers claimed are within the same in scope as what is described in the references above the office assumes that any property derived from those polymers is also necessarily the same. All of the applied references above teach the same coatings comprised of the same polymeric blends as claimed by applicants e.g. PCL and PHB. The polymers disclosed in those references also either recite or inherently teach the same  $T_g$  as claimed by applicants. It is well known in the art that the glass transition temperature  $T_g$  and the melting temperature  $T_m$  of a polymer is inherently linked to its crystalline structure. See Odian Principles of polymerization pp 24-33, cited previously. Thus it is the position of the examiner that since the polymers

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claimed are the same and their  $T_g$  values are the same the polymers will inherently have the same degree of crystallization as applicants claimed polymer blend because crystallinity and glass transition temperatures are inherently linked. Also applicants own specification at [0035] of the US PG PUB 20050112171 A1 states “the crystallinity of 3-PHB is about 80% while that of PCL is about 57%” thus as evidenced from applicants own specification it would appear that inherently 3-PHB (described as an additive) has a higher degree of crystallinity then PCL (described as a 1<sup>st</sup> polymer), thus since all of the above references teach blends of PCL and PHB the limitation is inherently met. It appears as though applicants are trying to claim an undisclosed or unknown property of an old polymeric blend. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3,6-8,11-15,17-18,20,23-25,28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 2001/0014717 A1).

Hossainy is described in the previous office action filed 04/18/2008. Hossainey while describing polymeric blends is silent on specific blend ratios. However adjusting

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the amounts of biodegradable polymers used as a coating for a stent is clearly a result effective parameter that one of ordinary skill in the art would adjust through routine optimization. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal blend ratio of polymers within a coating by adjusting the blend ratio and types of polymers to find the desired biodegradability of the coating itself and thereby also adjusting the release rate of any active contained within the coating. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of polymer blend ratio within a coating for a stent would have been obvious at the time of Applicant's invention. Furthermore it is noted by the examiner that a ratio of 1:1 is within applicants claimed blend ratios, it would be especially obvious that one of ordinary skill in the art would mix two polymers in a blend in equal amounts of 50:50.

Claims 1-3,6-8,11-15,17-18,20,23-25,28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (US 2004/0181271 A1).

DeSimone is described in the previous office action filed 04/18/2008. DeSimone while describing polymeric blends is silent on specific blend ratios. However adjusting the amounts of biodegradable polymers used as a coating for a stent is clearly a result effective parameter that one of ordinary skill in the art would adjust through routine optimization. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the

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optimal blend ratio of polymers within a coating by adjusting the blend ratio and types of polymers to find the desired biodegradability for the coating itself and thereby also adjusting the release rate of any active contained within the coating. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of polymer blend ratio within a coating for a stent would have been obvious at the time of Applicant's invention. Furthermore it is noted by the examiner that a ratio of 1:1 is within applicants claimed blend ratios, it would be especially obvious that one of ordinary skill in the art would mix two polymers in a blend in equal amounts of 50:50.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618